REMARKS

This responds to the Office Action dated October 5, 2005.

No claims are amended, canceled or added; as a result, claims 1, 3-8, 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33, 58-69 are now pending in this application.

Applicant respectfully traverses the finality of the Final Office Action as premature and respectfully requests withdrawal of the finality of the Rejections. Pursuant to M.P.E.P. § 706.07(a), second or any subsequent actions on the merits shall be final *except*, where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement. Further, according to M.P.E.P. § 707.07(g), "[p]iecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid ground available." Applicant respectfully submits a formal rejection of claim 69 was not provided in the Final Office Action dated October 5, 2005. Applicant respectfully requests review of claim 69 in the next Office Action and therefore respectfully requests withdrawal of the finality of the Final Office Action.

Information Disclosure Statement

Applicant submitted an Supplemental Information Disclosure Statement and a 1449 Form on November 23, 2004. Applicant respectfully requests that initialed copies of the 1449 forms be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

§102 Rejection of the Claims

Claims 1 and 3-8 were rejected under 35 U.S.C. § 102(e) as being anticipated by Maseda (U.S. Patent No. 6,514,237).

Claims 1, 3-6 and 8

Applicant respectfully traverses the rejections of claims 1, 3-6 and 8. Anticipation requires the disclosure in a single prior art reference of each element of the claim under

consideration. *In re Dillon* 919 F.2d 688 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). Moreover, "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be *identically* shown in a single reference." (Emphasis Added). *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). Applicant respectfully submits the rejections of claims 1, 3-6 and 8 fail because all of the elements are not identically shown in the cited reference. Applicant cannot find, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Claims 3-6 and 8 depend from claim 1 and thereby include all of its limitations.

Further, pursuant to M.P.E.P. § 2131, Applicant respectfully submits that Maseda fails to identically show in as complete detail, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, and incorporated in claims 3-6 and 8. According to M.P.E.P. § 2131, "the *identical invention* must be shown in the cited reference in as *complete detail as is contained in the claim*." (Emphasis added). *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1988). The Final Office Action states at page 2, section 3, "the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode . . . Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature." Applicant respectfully traverses this statement in so far as it fails to properly characterize the teaching of Maseda. Applicant can not find in Maseda, for instance, at least one electrode configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. In contrast, the only reference in Maseda to an electrode states:

> Ion-exchange polymer-noble metal composites are manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type electrodes. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement.

> The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.

Maseda, column 5, lines 1-19. Applicant respectfully submits the preceding quotation is the only teaching for an electrode in Maseda and does not appear to teach the *identical invention in as complete detail* as is contained in claim 1, and required by M.P.E.P. § 2131. Pursuant to M.P.E.P. § 2131, Applicant respectfully requests the Examiner show in Maseda where there is teaching for at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, and incorporated in claims 3-6 and 8. Absent such a showing, it appears that the Final Office Action relies on personal knowledge in making such an assertion. Pursuant to 37 C.F.R. § 1.104(d)(2), Applicant traverses the assertion and respectfully requests the Examiner submit an affidavit providing support for the assertion with the next Office Communication or withdraw this line of argument.

Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

Claim 7

Applicant respectfully submits the rejection of claim 7 fails because all of the elements are not identically shown in the cited reference. Applicant cannot find, the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7. Moreover, Applicant respectfully traverses the Final Office Action statement at page 3, first full paragraph, "The fact that the electroactive material at the distal end of the device body must be connected to a power supply at the proximal end as per col. 5, lines 40-55 dicates that the lead body be configured to be coupled to a pulse generator." Pursuant to M.P.E.P. § 2131, "the *identical invention* must be shown in the cited reference in as *complete detail as is contained in the claim.*" (Emphasis added). Maseda states at column 5, lines 41-43, "The control module 300 preferably comprises a power supply capable of supplying both DC voltage/current and AC voltage/current at various frequencies." Pursuant to M.P.E.P. § 2131, Applicant respectfully requests the Examiner show in Maseda where there is teaching for a

device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7.

Further, Applicant respectfully submits claim 7 is patentable at least as a dependent claim of patentable base claim 1, and the discussion for claim 1 above is repeated in support of claim 7.

Reconsideration and allowance of claim 7 are respectfully requested.

§103 Rejection of the Claims

Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lieber et al. (U.S. Patent No. 4,329,993) in view of Maseda (U.S. Patent No. 6,514,237).

Applicant respectfully traverses the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 for at least the following reasons.

I. The Final Office Action Fails to Maintain a *Prima Facie* Case of Obviousness Because Lieber Teaches Away From the Claims.

Because Lieber teaches away from the proposed combination the Final Office Action does not identify a proper motivation to combine Lieber with Maseda. Applicant respectfully traverses the Final Office Action statements at page 3, last paragraph, "Maseda, however, teaches that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous from the standpoint of increasing flexibility and steerability of the catheter as it is introduced into the body. Increased maneuverability through the tortuous vasculature system, high precision, and ease of placement – very important design considerations for the medical artisan – make the incorporation of the Maseda assembly and related control system on the medical device of Lieber et al. an obvious choice." Pursuant to M.P.E.P. § 2143.03, "Prior art must be considered in its entirety, including disclosures that teach away from the claims." Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131

(Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). Applicant submits, Lieber states at column 3, lines 52-64, "In use, the soft, pliable catheter body . . . is advanced, with the balloon in deflated or only partially inflated condition, into the right atrium 12. The balloon is then inflated to its maximum recommended capacity and the *flow of blood through the heart rapidly propels the inflated balloon-tipped catheter from the right atrium into the pulmonary artery 18* (FIG. 1). It will be observed that when the catheter is so positioned, *balloon 26 has advanced through the pulmonary artery into what is generally referred to as the pulmonary capillary wedge position.*" (Emphasis added).

Lieber teaches away from the proposed combination because Lieber advises using an inflated balloon-tipped catheter propelled from the right atrium and into the pulmonary artery as opposed to at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claims 9 and 23. Claims 10, 12-14, 16, 21, 22 and 58 depend from claim 9 and thereby include all of its limitations. Claim 26 depends from claim 23 and thereby includes all of its limitations. Additionally, Lieber teaches away from the proposed combination because Lieber advises using an inflated balloon-tipped catheter propelled from the right atrium and into the pulmonary artery as opposed to means for electrically stiffening at least one assembly and the device body, wherein electrical current is applied to the at least one assembly, as recited in claim 28. Claims 29 and 33 depend from claim 28 and thereby include all of its limitations. Further, Lieber teaches away from the proposed combination because Lieber advises using an inflated balloon-tipped catheter propelled from the right atrium and into the pulmonary artery as opposed to a first assembly and second assembly including a rheometric material, and the rheometric material of at least one of the first assembly and the second assembly contracts and/or stiffens when electrical current is applied thereto, as recited in claim 59. Claims 60-64 depend from claim 59 and thereby include all of its limitations. Further still, Lieber teaches away from the proposed combination because Lieber advises using an inflated balloon-tipped catheter propelled from the right atrium and into the pulmonary artery as opposed to a rheometric material electrically coupled with a second electrode, the rheometric material contracts and/or stiffens when electrical

current is applied thereto, as recited in claim 65. Claims 66-68 depend from claim 65 and thereby include all of its limitations.

Because Lieber teaches away from the proposed combination, Applicant can not find any objective suggestion in Lieber to employ, for example, the structure described above, for claims 9, 23, 28, 58 and 65. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to combine Lieber with Maseda in the manner proposed or withdraw this line of argument.

II. The Final Office Action Fails to Maintain a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Combine Lieber with Maseda.

Further, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the Final Office Action does not identify a proper motivation to combine Lieber with Maseda. According to M.P.E.P. § 2143.01, the mere fact that references *can* be combined does not render the resultant combination obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of the combination. The Final Office Action does not state how Maseda would be in need of, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claims 9, 23, 28, 59 and 65 and incorporated in dependent claims 10, 12-14, 16, 21, 22, 26, 29, 33, 58, 60-64 and 66-68. Applicant cannot find any objective suggestion in Maseda to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to combine Lieber with Maseda in the manner proposed.

III. The Final Office Action Fails to Maintain a *Prima Facie* Case of Obviousness Because the Final Office Action Does Not Consider the Claims as a Whole.

Further still, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the rejection does not consider the claims as a whole. According to MPEP § 2141.02, In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious. (Emphasis in original). *Stratoflex, Inc. v.*

Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The Final Office Action at page 3, last paragraph states, "Lieber et al. disclose a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teach that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous." In contrast, claim 9 recites that the medical device includes, *in combination with all of the elements of claim 9,* at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto. Additionally, claim 23 recites that the medical device includes, *in combination with all of the elements of claim 23,* at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when current is applied thereto. Further, claim 28 recites that the medical device includes, *in combination with all of the elements of claim 23*, means for electrically stiffening the at least one assembly and the device body, wherein electrical current is applied to the at least one assembly. Further still, claim 59 recites that the medical device includes, *in combination with all of the elements of claim 59*, the first assembly and the second assembly including a rheometric material, and the rheometric material of at least one of the first assembly and the second assembly contracts and/or stiffens when electrical current is applied thereto. Moreover, claim 65 recites that the medical device includes, *in combination with all of the elements of claim 65,* a rheometric material electrically coupled with the second electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto. As described above, the Final Office Action fails to show teaching or suggestion for this new combination. Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established.

Further, by failing to consider the invention as a whole, the Final Office Action uses Applicants' disclosure as a template and performs hindsight reconstruction to selectively

combine Maseda with Lieber in the proposed manner. According to *In re Vaeck*, the teaching or suggestion to make the claimed device must be found in the prior art, not in the Appellants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

Response to Arguments

I. The Final Office Action Refuses to Give Patentable Weight to Functional Language in the Claim

Applicant respectfully traverses the statements in the Final Office Action at page 5, first paragraph, "The examiner cannot find in the claim where it is stated that the electrode must perform transmission and reception of electrical signals to and from tissue. The examiner cannot find any structure in the claim for generating such signals and sensing such signals." The Final Office Action refuses to give patentable weight to at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Pursuant to M.P.E.P. § 2173.05(g), "[a] functional limitation *must be evaluated and considered*, just like any other limitation of the claim . . . A functional limitation is often used in association with an element . . . to *define a particular capability or purpose that is served by the recited element*." (Emphasis added). See also *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); *In re Caldwell*, 138 USPQ 243 (CCPA 1963); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987) ("so that" functional clause of claim renders reference non-anticipating).

II. The Final Office Action Fails to Identically Show Every Element of the Claimed Invention in Maseda

Moreover, as stated above, anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon* 919 F.2d 688 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). Further, "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be *identically* shown in a single reference." (Emphasis Added). *In re Bond*, 910 F.2d 831 (Fed.

Cir. 1990). Applicant respectfully submits the rejection of claim 1 fails because all of the elements are not identically shown in the cited reference. Applicant cannot find, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Claims 3-8 depend from claim 1 and thereby include all of its limitations.

Further, according to M.P.E.P. § 2131, "the *identical invention* must be shown in the cited reference in as *complete detail as is contained in the claim*." (Emphasis added). *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1988). The Final Office Action states at page 5, first paragraph, "The platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive bodily fluids. The platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from the tissue." Applicant respectfully traverses this assertion in so far as it fails to properly characterize the teaching of Maseda. Applicant can not find in Maseda, for instance, at least one electrode configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. In contrast, the only reference in Maseda to an electrode states:

> Ion-exchange polymer-noble metal composites are manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type electrodes. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement. The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.

Maseda, column 5, lines 1-19. Applicant respectfully submits the preceding quotation is the only teaching for an electrode in Maseda and does not appear to teach the *identical invention in as complete detail* as is contained in claim 1, and required by M.P.E.P. § 2131. Pursuant to M.P.E.P. § 2131, Applicant respectfully requests the Examiner show in Maseda where there is teaching for at least one electrode coupled with the device body, where the at least one electrode

is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, and incorporated in claims 3-6 and 8. Absent such a showing, it appears that the Final Office Action relies on personal knowledge in making such an assertion. Pursuant to 37 C.F.R. § 1.104(d)(2), Applicant traverses the assertion and respectfully requests the Examiner submit an affidavit providing support for the assertion with the next Office Communication or withdraw this line of argument.

III. The Final Office Action Fails to Establish a *Prima Facie* case of Inherency

Furtherstill, Applicant respectfully traverses the Final Office Action statement at page 5, first paragraph, "Platinum electrodes are *inherently* capable of transmitting and receiving electrical signals to and from the body due to their conductive and biocompatible nature." (Emphasis added). To serve as an anticipation when a reference is silent about the asserted inherent characteristic, the gap in the reference may be filled with recourse to extrinsic evidence. But, such evidence must make clear that "the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). (Emphasis added). Moreover, the Examiner must establish a *prima facie* case of inherency. As recited in M.P.E.P. § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis added). Applicant respectfully submits that the Final Office Action has not produced extrinsic evidence to show that at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 is *necessarily* present in Maseda. Further, the Final Office Action has not provided a *prima facie* showing of technical reasoning to support the conclusion at page 5, first paragraph of the Final Office Action that, "the platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from tissue." Instead, the Final Office Action only argues that "the platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to

come into contact with tissue or conductive body fluids." Final Office Action, page 5, first paragraph.

Reconsideration and allowance of claims 1 and 3-8 are respectfully requested.

Documents Cited But Not Relied Upon in this Office Action

Applicant has reviewed the references made of record and not relied upon, but does not find them to be any more relevant than the patents discussed in the Final Office Action. Because the references are not made part of the rejections of this Final Office Action, Applicant need not address the additional reference. Applicant reserves the right to further address any rejections therefrom.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5 day of December, 2005.

Paula Sucha
Name

Paula Sucha
Signature